

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type  <input type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOW UP <input type="checkbox"/> EXEMPTION		2. Type of Mechanism  <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER:		3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.	
4. Title of Application or Activity				5. Name of Principal Investigator, Program Director, Fellow, or Other	

☐ This Assurance, on file with the Department of Health and Human Services, covers this activity:  
Assurance Identification no. M— IRB identification no. \_\_\_\_\_

☐ This Assurance, on file with (*agency/dept.*) \_\_\_\_\_ , covers this activity.  
Assurance Identification no. \_\_\_\_\_ IRB identification no. \_\_\_\_\_ (*if applicable*)

☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon re

☐ *Exemption Status:* Human subjects are involved, but this activity qualifies for exemption under Section 101 (b), paragraph

☐ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on

(date) \_\_\_\_\_ by: ☐ Full IRB Review or ☐ Expedited Review.

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

## 8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution
11. Phone No. <i>(with area code)</i>	12. Fax No. <i>(with area code)</i>	
13. Name of Official		14. Title
15. Signature		16. Date